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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/089,287 | 03/26/2002 | Denis Labarre | 427.056 | 9376 |

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NEW YORK, NY 10016

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|----------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--|
| <p align="center">Office Action Summary</p> | <p>Application No.</p> <p>10/089,287</p> | <p>Applicant(s)</p> <p>LABARRE ET AL.</p> | |
| | <p>Examiner</p> <p>Blessing M. Fubara</p> | <p>Art Unit</p> <p>1615</p> | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time filed 08/16/04; request for continued examination under 37 CFR 1.114, amendment and remarks filed 08/23/04; and supplemental response and remarks filed 11/19/04. Claims 1-21 and 28-31 are pending.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-18, 20, 21 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by El et al. (WO 98/08897, English translation provided by applicants).

El discloses cross-linked copolymers that are based on non cross-linked polycarboxylic polymers and cross-linking agent, which has at least two amine functions; the cross-linked copolymer comprises at least one polycarboxylic polysaccharide and at least one non cross-linked polycarboxylic polymer that is not a polycarboxylic polysaccharide (page 1, line 16 to page 2 line 5). The non cross-linked polycarboxylic polysaccharide is selected from glycosaminoglycan, pectinic acid (pectin), alginic acid, carboxymethyldextran, carboxymethylcellulose (page 2, lines 6-11 and 21-24) and these polysacchrides are not polycarboxylated. Non polysaccharide polycarboxylic polymers are selected form poly(glutamic acid), poly(aspartic acid), poly(acrylic acid), poly(methacrylic acid) and EUDRAGIT L and S (page 2, lines 11-15). The cross-linking agents are selected from polyamines, triamines, and diamines, proteins, polylysine, chitosan and melamine and spermine, and hexanediamine is specifically disclosed diamine (page 3, lines 6-19). El discloses degradation of the polycarboxylic polysaccharide in the composition by the flora of the colon

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(page 7, lines 1 and 2). El also discloses a method of preparing the cross-linked polymer where the method comprises reacting the non cross-linked polycarboxylic polymers in the presence of an activators and a cross-linking agent that comprises at least two amines, in an aqueous medium (page 4, lines 3-7). The activator is selected from carbodiimides, quinoline and mixed anhydrides (page 5, lines 12-23). The composition of El comprises active ingredients such as 5-aminosalicylic acid, antineoplastic agents, antispasmodic and chemotherapeutic agents (page 7, lines 8-19), and inert support or excipient, which is at least one cross-linked co-polymer (page 6, lines 1-3). The teaching of El meets the limitations of the claims.

Applicants argue that the reaction to form the cross-linked copolymer is between copolymers.

3. Applicants' arguments filed 11/19/04 have been fully considered but they are not persuasive. The polymers are the same as those recited in claims 3.

4. Claims 1-18, 20, 21 and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert et al. (US 6,229,009).

Lambert discloses cross-linked copolymer that is based on at least one non-cross-linked polycarboxylic polysaccharide and at least one second non-cross-linked polycarboxylic polymer that is not a polycarboxylic polysaccharide (abstract). The non-cross-linked polysaccharide is selected from glycosaminoglycans, pectinic acid, alginic acid, carboxymethyldextran and carboxymethylcellulose (column 1, lines 49-56). The non-saccharidic polycarboxylic polymer is selected from poly(glutamic acid), poly(aspartic acid), poly(acrylic acid), poly(methacrylic acid) and EUDRAGIT L and S (column 1, lines 57-62). The cross-linking agent comprises at least two amine functions and examples are polyamines, triamines, diamines, proteins and

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hexdiamine is an example of a diamine (column 2, lines 20-39). Lambert also discloses a process for preparing the cross-linked copolymer and the process comprises reacting non-cross-linked polycarboxylic polymers with the cross-linking agent that has at least two amine functions, in the presence of an activator and the reaction is carried out in an aqueous media (column 2, line 52 to column 3 line 36). The activator is selected from carbodiimides, quinoline derivatives or mixed anhydride (column 3, lines 37-54). Lambert further discloses a pharmaceutical composition that comprises at least one active agent, at least one cross-linked copolymer as an inert support or excipient (column 3, lines 59-66); the composition is degradable by the flora of the colon and can be directly administered at the level of the colon (column 4, lines 25-32 and 40-47). See also claims 1, 2 and 4-21. The teachings of Lambert meet the limitations of the claims.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over El et al. (WO98/08897) in view of Heidel et al. (US 5,219,971).

El clearly teaches the cross-linked polymers of the instant application except that the reaction of the non-saccharidic polymer with the polysaccharide is not done in an inert atmosphere. However, Heidel discloses grafting olefinically unsaturated carboxylic acid onto a polysaccharide in the presence of nitrogen (abstract, column 4, line 65 to column 7 line 13 and example 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time

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the invention was made to prepare the cross-linked polymer of EI in aqueous medium. One having ordinary skill in the art would have been motivated to prepare the polymer in the absence of air with the expectation of polymerizing the non cross-linked copolymers.

Double Patenting

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 4-6, 9-12, 14, 17, 18, 20 and 21 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 4-9, 13, 14, 16, 17 and 18 of prior U.S. Patent No. 6,229,009. Claim 1 is identical in scope compared to claim 1 of US 6,229,009 even though the wording between the claims is slightly different. Note that claim 1 is a cross-linked copolymer prepared from a reaction between a cross-linking agent that has at least two amine functions and non-cross-linked polycarboxylic copolymer where the non-cross-linked polycarboxylic copolymer comprises at least one non-cross-linked polysaccharide and at least one non-saccharidic non-cross-linked polymer and where at least one of the non-saccharidic non-cross-linked polymer is polycarboxylic. This is a double patenting rejection.

9. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,229,009. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim because the examined claim is either anticipated by or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 is generic to all that is recited in claim 11 of US 6,229,009. That is claim 11 of US 6,229,009 falls entirely within the scope of claim 13, or in other words, claim 13 is anticipated by claim 11 of US 6,229,009.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

